

device is being tested for better diagnostic imaging of a potentially cancerous lump in the breast that has already been detected and shows great promise. But it is not known whether the new machine can be used effectively in screening for breast cancer when there are no symptoms. Under this bill, if a manufacturer seeks approval for a digital mammography machine that is clearly designed for breast cancer screening, not just for diagnosis, the FDA would be prohibited from requiring data to show that the machine is effective for screening. Does the Senate really want to support legislation that could result in women dying needlessly from undetected breast cancer? That is what this device provision could cause.

We know that there is more money that is going to be made by those particular companies that can get on the market faster than their competitor through this loophole. Is that what we are about in terms of trying to protect the public? The FDA is the principal agency of the government to protect the health and safety.

The various professionals in consumer organizations and patient organizations that spend every day trying to protect the public health understand the dangers that are involved in this provision. They are all saying why doesn't the Senate build in these protections?

But no. There is that majority in the United States Senate that would go ahead and accept this, and pass this legislation as it is without the adequate protections. And, unless the public is going to understand that this is something which is important and let their representatives understand that by Tuesday next, that is what will happen.

The President of the United States has had the courage to say no to this particular provision, because he understands, as the Secretary of Health and Education understands, and as the public health community understands the dangers to the American consumer if we let this provision continue.

Mr. President, I want to review as clearly as I can exactly what the bill that is before us, S. 830, does. It prohibits the FDA from reviewing the safety of a device for uses not listed by the manufacturer.

Senator REED's amendment will prohibit the FDA from reviewing the safety of a device for uses not listed by the manufacturer unless the label is "false or misleading." You would think we would get 100 votes on that. Is the Senate going to say, "OK, it is going to be all right for device manufacturers to have false and misleading labels?"

Other examples in the way that this provision could allow unsafe and ineffective devices abound. A stent designed to open the bile duct for gallstones could be modified in a way that clearly was designed to make it a treatment for blockages of the carotid artery. Without adequate testing, it

could put patients at risk of stroke or death. But under this bill, the FDA would be prohibited from looking behind the label to the actual intended use of the device.

Mr. President, the vast majority of medical device manufacturers meet high ethical standards. Most devices are fully tested and evaluated by the FDA before they are marketed. But as many examples make clear, if the FDA does not have adequate authority to protect innocent patients, the result can be unnecessary death and injury to patients across the country. There is no justification—none whatever—for Congress to force the FDA to approve devices with false or misleading labels.

Each and every time amendments to medical device and pharmaceutical provisions have been approved by the Congress, Republican and Democrat, the public health and safety of the American people has been enhanced. There are provisions in this legislation that will do so. But not this provision. This provision, if left to stand, poses significant health risks to American consumers.

We ought to be making sure that when the FDA gives their stamp of approval, that devices are going to be safe and efficacious, and that every doctor in this country and every patient knows they are going to meet the highest safety standards. That ought to be our commitment to the American people.

But this particular provision does not do it. Rather than being a step forward, it is a significant and dangerous step backward. Unscrupulous manufacturers do not deserve a free ride at the expense of public health.

We have good legislation that is going to extend the PDUFA which is going to mean that we will have many excellent additional professional people to help to move various pharmaceutical products onto the market sooner.

The public health organizations know what is happening out there, and they have pleaded with all of us in the Senate and said, My God, for once put the profits of this handful of industries that is trying to circumvent the health and safety protections of the American people, put that aside and make sure, when you act next week, the roll will be called, act to protect the public here in the United States.

That is what this debate is about. That is what we will have a chance to vote on next week.

Mr. President, I believe my time is just about up. I thank the Chair. We will have an opportunity to go back to this tomorrow morning at 9:30 to add additional information. We hope we will hear from the American people if they care about assuring that their children are going to have safe medical devices, that their parents are going to have safe medical devices, that their daughters and their husbands, their grandparents are going to have safe medical devices. There is only one way

to do it, and that is on next Tuesday when the rollcall comes, Senators will support the Reed amendment, which I welcome the opportunity to cosponsor, which will be the most important action we can take in the Senate on this legislation to protect the health and safety of the American people.

Mr. President, I yield the floor.

#### ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

The PRESIDING OFFICER. Under the previous order, the Senate stands adjourned until 9:30 a.m. Friday, September 19.

Thereupon, at 11:26 p.m., the Senate adjourned until Friday, September 19, 1997, at 9:30 a.m.

#### NOMINATIONS

Executive nominations received by the Senate September 18, 1997:

##### SECURITIES AND EXCHANGE COMMISSION

PAUL R. CAREY, OF NEW YORK, TO BE A MEMBER OF THE SECURITIES AND EXCHANGE COMMISSION FOR THE TERM EXPIRING JUNE 5, 2002, VICE STEVEN MARK HART WALLMAN, TERM EXPIRED.

LAURA S. UNGER, OF NEW YORK, TO BE A MEMBER OF THE SECURITIES AND EXCHANGE COMMISSION FOR THE TERM EXPIRING JUNE 5, 2001, VICE J. CARTER BEESE, JR., RESIGNED.

##### DEPARTMENT OF JUSTICE

JOSE GERADO TRONCOSO, OF NEVADA, TO BE U.S. MARSHAL FOR THE DISTRICT OF NEVADA FOR THE TERM OF 4 YEARS, VICE HERBERT LEE BROWN.

##### IN THE COAST GUARD

THE FOLLOWING CADETS OF THE U.S. COAST GUARD ACADEMY FOR APPOINTMENT TO THE GRADE INDICATED IN THE U.S. COAST GUARD UNDER TITLE 14, UNITED STATES CODE, SECTION 211:

##### To be ensign

STEVEN C. ACOSTA, 0000  
STERLING V. ADLAKHA, 0000  
MARCIE L. ALBRIGHT, 0000  
KATIE R. ALEXANDER, 0000  
JEREMY J. ANDERSON, 0000  
WILLIAM L. ARMITT, 0000  
LEANNE M. BACON, 0000  
MATTHEW J. BAER, 0000  
ABRAHAM C. BANKS, 0000  
GREGORY R. BARBIAUX, 0000  
JONATHAN BATES, 0000  
PAUL R. BEAVIS, 0000  
SEAN C. BENNETT, 0000  
CHANDLER BENSON, 0000  
CHERYL A. BEREZNY, 0000  
BRENT R. BERGAN, 0000  
ALEX W. BERGMAN, 0000  
JAMES B. BERNSTEIN, 0000  
JASON M. BIGGAR, 0000  
BRYAN R. BLACKMORE, 0000  
ANNE M. BLANDFORD, 0000  
ROBERT R. BOROWCZAK, 0000  
JOHN B. BRADY, 0000  
MARC BRANDT, 0000  
THOMAS K. BRASTED, 0000  
MARK A. BRAXTON, 0000  
VERONICA A. BRECHT, 0000  
JASON A. BRENNELL, 0000  
JOSEPH D. BROWN, 0000  
RANDALL E. BROWN, 0000  
DAVID L. BURGER, 0000  
KATRINA D. BURRITT, 0000  
ERIN E. CALVERT, 0000  
GREGG W. CASAD, 0000  
GEORGE B. CATHIEY, 0000  
KEMBERLY B. CHAPMAN, 0000  
SCOTT A. CLEMENTZ, 0000  
JENNIFER J. COOK, 0000  
THOMAS D. CRANE, 0000  
CHARLES C. CULOTTA, 0000  
KENNETH C. CUTLER, 0000  
THOMAS C. D'ARCY, 0000  
THOMAS W. DENUCCI, 0000  
FREDERICK D. DETAR, 0000  
ALEXANDER D. DODD, 0000  
ROGER S. DOYLE, 0000  
JOHN M. DUNLAP, 0000  
REGINALD C. EISENHAEUER, 0000  
MEREDITH M. ENGELKE, 0000  
BRIAN C. ERICKSON, 0000  
ANTHONY S. ERICKSON, 0000  
JOSHUA W. FANT, 0000  
LOUIS B. FAULKNER, 0000  
GREGORY J. FERRY, 0000